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| 10/596,024 | 05/15/2007 | Elzbieta Mietkiewska | PAT 989W-2 | 1829 |
| 26123 7590 04/01/2010 BORDEN LADNER GERVAIS LLP Anne Kinsman WORLD EXCHANGE PLAZA 100 QUEEN STREET SUITE 1100 OTTAWA, ON K1P 1J9 CANADA | | | | |
| EXAMINER | | | | |
| KUMAR, VINOD | | | | |
| ART UNIT | | PAPER NUMBER | | |
| 1638 | | | | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ipinfo@blgcanada.com

Office Action Summary

Application No.

10/596,024

Applicant(s)

MIETKIEWSKA ET AL.

Examiner

VINOD KUMAR

Art Unit

1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 December 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 24-43 is/are pending in the application.
- 4a) Of the above claim(s) 24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 25-43 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 December 2009 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-8506)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date 2/17/2010, 10/27/2009

DETAILED ACTION

Status of objections and rejections

1. Applicant's responses filed 12/29/2009, 1/4/2010 and 2/17/2010 are entered.
2. Claims 1-23 are cancelled by the Applicant. Claims 24-43 are newly introduced claims.
3. All previously made objections and rejections are withdrawn in light of Applicant's amendment filed in the paper of 12/29/2009.
4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Election/Restrictions

5. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is to elect a single invention to which the claims must be restricted. In the instant case, claims newly added 25-43 fall within the scope of claims 1-23 (now cancelled) are thus would be regarded as elected invention by original presentation.

Group I, claim(s) 24, drawn to a polypeptide having fatty acid elongase activity.

Group II, claim(s) 25-43, drawn to a nucleic acid molecule comprising a nucleotide sequence encoding a fatty acid elongase, an expression vector, cell, seed, plant or a method of increasing C20 or greater fatty acid proportion in a plant comprising said nucleic acid molecule.

Applicants are also reminded that different nucleotide sequences and amino acid sequences are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute different inventive concepts.

Accordingly, Groups I-II are not so linked by the same or a corresponding special technical feature as to form a single general inventive concept.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently

named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Accordingly, claim 24 is withdrawn from further consideration. Claims 25-43 are examined on merits. This restriction has been necessitated by Applicant's amendment filed in the paper of 12/29/2009. Accordingly, this restriction would be considered FINAL.

Claim Objections

6. Newly added claim 27 is objected to because of the following informalities:

Newly added claim 27 is objected for having improper article before "nucleic acid" in line 1. It is suggested to change "a" to --the--.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

7. Newly added claims 41-43 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Newly added claim 41 recites the limitation "a plant as defined in claim 35" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Dependent claims are also rejected because they fail to overcome the deficiency of claim 41.

Claim Rejections - 35 USC § 103

8. Newly added claims 25-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over James et al. (CA 2,203,754 (WO 96/13582), Issued May 9, 1996) in view of Jaworski et al. (US Patent Publication No. 20020049994, Published April 25, 2002) .

James et al. teach polynucleotide sequences from both the *Arabidopsis* FAE1 gene and *B. napus* FAE1 gene. The reference further teaches DNA constructs comprising the polynucleotide sequences that are used to modify FAE1 gene expression and thereby modulating fatty acid content in plant organs, particularly seeds. The reference further teaches transgenic plants (*Brassica* plants) comprising a recombinant expression cassette which includes a plant promoter operably linked to the polynucleotide sequence taught in the reference. The reference also teaches the use of said DNA construct in broad range of plants including *Linum* (flax), *Simmondsia* and *Limnathes*. The reference also teaches that FAE1 polypeptide may also be expressed in a microorganism host, such as bacteria or yeast. The reference also teaches that overexpressing FAE1 gene in a seed increases the proportion of C20 or greater fatty acids (including erucic acid content) in said seed. The reference also teaches extracting or obtaining oil from said seeds. See in particular, page 8, line 21 through page 9, line 3; page 10, lines 26-27; claims 1-26.

James et al. do not teach *Crambe* fatty acid elongase as set forth in instant SEQ ID NO: 24.

Jaworski et al. teach a nucleic acid sequence encoding a fatty acid elongase 1 polypeptide of SEQ ID NO: 34 having 97% sequence identity to instant SEQ ID NO: 24. The reference further teaches DNA constructs comprising said polynucleotide sequence to modulate fatty acid content in plant organs, particularly seeds. The reference further teaches transgenic plants (*Brassica* plants) comprising a recombinant expression cassette which includes a plant promoter operably linked to the polynucleotide sequence taught in the reference. The reference also teaches the use of said DNA construct in broad range of plants including *Crambe abyssinica*, flax and *Brassica sp.* The reference also teaches that said polypeptide may also be expressed in a microorganism host, such as bacteria or yeast to increase C20 or C22 fatty acid content. The reference also teaches that overexpressing said polypeptide in a seed increases the proportion of C20 or greater fatty acids (including erucic acid

content) in said seed. The reference also teaches extracting or obtaining oil from said seeds. See in particular, claims 1-23; paragraphs 0001-0138; examples 1-4.

Given the use of elongase enzymes from *Arabidopsis*, *Brassica* and other plant species, including the one taught by Jaworski et al. share identical enzymatic activities for modulating fatty acid content in a plant as asserted by James et al., it would have been obvious and within the scope of an ordinary skill in the art to have used any fatty acid elongase gene including the one from Jaworski et al. *Crambe abyssinica* plant as a part of normal design procedure and regardless of its source in modulating fatty acid content in a plant, and thus arrive at the claimed invention with a reasonable expectation of success.

Given that Jaworski et al. polynucleotide sequence encoding FAE1 (SEQ ID NO: 34) is highly homologous to instant SEQ ID NO: 25 encoding FAE1 of SEQ ID NO: 24, and which exhibits elongase activity in increasing C20 or greater fatty acid proportion (including erucic acid content) in transgenic plant cell, it would have been obvious and within the scope of an ordinary skill in the art at the time the invention was made to isolate and identify claimed nucleotide sequences (variants of Jaworski et al. polynucleotide sequence encoding SEQ ID NO: 34) based on the polynucleotide sequence encoding Jaworski et al. SEQ ID NO: 34 by applying conventional methodologies of variant DNA isolation which had a reasonable expectation of success.

It would have been prima facie obvious, and within the scope of an ordinary skill in the art at the time the claimed invention was made to choose from a finite number of predictable variants of a nucleotide sequence encoding Jaworski et al. polypeptide of SEQ ID NO: 34 with a reasonable expectation of success of producing transgenic plants having increased C20 or greater proportion of fatty acids, including increase in erucic content.

See the recent Board decision *Ex parte Smith*, -- USPQ2d --, slip op. at 20, (Bd. Pat. App. &

Interf. June 25, 2007) (citing *KSR*, 82 USPQ2d at 1396). *KSR* forecloses the argument that a **specific** teaching, suggestion or motivation is required to support a finding of obviousness.

Thus, the claimed invention as a whole is prima facie obvious over the teachings of the prior art.

Conclusions

9. Newly added claims 25-43 are rejected.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vinod Kumar whose telephone number is (571) 272-5444. The examiner can normally be reached on 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Vinod Kumar/
Primary Examiner, Art Unit 1638